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The Regulation of Toothpaste

Food is the **very** sustenance of life for humans. Perhaps no body structures are more crucial to human consumption of food than our teeth. The teeth serve to break up larger pieces of food into smaller, more digestible bits that our bodies can use. Teeth are always subject to decay from the various food particles that are constantly brushed against them, occasionally left undetected there for several hours. Humankind invented toothpaste for a variety of reasons, the most important of which is the prevention of this tooth decay. Others include the freshening of breath, and the whitening or strengthening of the teeth. Usually, we, the buying public, do not see this product until it is in its familiar plastic tubing at the supermarket, complete with an easy-to-read (usually) label and brand name conveniently on the front. However, before their product reaches the shelves, manufacturers of toothpaste in this country are regulated by the Food and Drug Administration with various practices designed to protect the public. These practices include official FDA standards on toothpaste safety and effectiveness, as well as regulation of how much and which kind of ingredients are permitted in the formula. There are also strict standards involving the labeling of the toothpaste, as established in the FDA's final monograph for anticaries drug products. Lastly, a brief look at toothpaste regulation in other countries will serve to show the relative severity of regulation practiced by the FDA.

Classification of Toothpaste Under the 1938 Act

Since its enactment in 1938, administration of the **Federal Food Drug and Cosmetic Act** has fallen on the Food and Drug Administration (FDA). The 1938 Act brought cosmetics and medical devices under the statute, in addition to the foods and drugs already within its scope before 1938. Under the Act, foods are regulated differently than cosmetics, which are in turn dealt with differently than drugs. The placing of toothpaste into one of these three categories is more complex than it first may seem. Section 321 of the Act defines food as (1) articles used for food or drink in man or other animals, (2) chewing gum, and (3) articles used for components of any such article.¹ Clearly, toothpaste does not fall into this category. Humans and other animals do not eat this product, nor do they intentionally consume any of it at all. The next category in the Act is drugs, which are defined briefly as (A) any article recognized in any of the official national drug publications or a supplement thereof, and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (C) articles (other than food) intended to affect the structure or any function of the body.² Subpart (B) of this definition makes a good case for the inclusion of toothpaste, as one of the main purposes of toothpaste is the prevention of tooth decay, known as caries. Under the statute, toothpaste is likely ruled out of the medical device category because it achieves its primary intended purposes through chemical action within the body.³ Lastly, there is the

21	U.S.C.	§321(f) (1938)
21	U.s.c.	§321(g) (1)
21	U.s.c.	§321(h)

cosmetic category, which also could include toothpaste. These are defined as articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced to, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. Again, toothpaste could fall under this category since it could be said that its purposes are cleansing and beautifying the teeth.

The FDA has spoken in the Federal Register as to how the distinction between a drug and a cosmetic is to be determined. The FDA has stated that the intended use of a product is the primary determining factor as to whether a product is a drug, a cosmetic, or both.⁴ This intended use may be inferred from the product's labeling or advertising, as well as from any other relevant factor, including the presence of particular ingredients.⁵ The presence of a known therapeutic ingredient can cause a product to be regulated as a drug, even in the absence of drug claims. Along these lines, the FDA has decided that all toothpastes or other dentifrices which contain fluoride will indeed be regulated as drugs, regardless of whether or not any drug claims have been made.⁶ The Agency reasons that fluoride is widely accepted as an anti-cavity agent by the dental products industry and consumers, and because fluoride affects the structure of the tooth.⁷ The Agency has also stated that intended use can be demonstrated by evidence that (1) drug-like effects in a large proportion of users are foreseeable by the reasonable manufacturer, (2) consumers use the product predominantly for its significant pharmacological effects, or (3)

~ 59 Fed. Reg. 5226, 5227 (1994)

- National Nutritional Foods Association v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977)

59 Fed. Reg. 6084, 6088 (1994)

60 Fed. Reg. 41453 (1995)

manufacturers know that the product will be used for these drug-like effects.⁸ This drug classification reflects a general decision on FDA's part that toothpastes are indeed used primarily for the prevention of disease; in truth, such products are labeled as anticaries agents in all versions of the FDA's monograph for such products, and nearly all tubes of toothpaste contain somewhere on the label the message that the product fights cavities and/or prevents tooth decay.

This explanation would seem to leave open the possibility that a toothpaste could be regulated at least partially as a cosmetic if its main claims were for the beautification of the teeth, and not the prevention of caries. The FDA has ruled that if a product is intended for use as both a drug and as a cosmetic, it must comply with all of the specifications found for the drug within the FDA final monograph, plus it must bear the applicable labeling for cosmetic use in conformity with 21 U.S.C. §362.⁷ However, achieving a cosmetic status for any type of toothpaste or dentifrice would be a difficult task, since most such products do contain some amount of fluoride, a proven cavity fighter, and would thus automatically be regulated as a drug. The FDA has also explained that, in the case of toothpastes, the cosmetic function of attractive teeth is accompanied by the drug mechanism of preventing cavities, and it has thus prohibited cosmetic status on these grounds. One can only surmise that it would still be possible to have a toothpaste regulated as a cosmetic, but this would not be a toothpaste in the traditional sense. A cosmetic toothpaste would likely have to contain no known therapeutic or drug-like ingredients, and be marketed, labelled, intended, and primarily used as a cosmetic. An example might be a toothpaste offered

⁷ 58 Fed. Reg. at 47611 (1993)
⁸ 59 Fed. Reg. 5226, 5227 (1994)

solely to smokers to whiten their stained teeth, with no anti-caries indications. An additional comment on the label specifying that the product is not an anti-cavity agent and that another anti-caries toothpaste should be used in conjunction with this product could only help the cause. It is unclear how such actions would fare in court, since the ingredients approach to classification has not been tested adequately nor applied consistently by courts or by the FDA.¹⁰

Are Certain Toothpastes New Drugs?

In order to better protect the public from drugs that are unsafe or ineffective, the FDA strictly limits the drugs that may be entered into interstate commerce without first being reviewed and approved by the Agency. This FDA power, however, does not extend over all drugs; drugs that are not defined as new drugs under the statute may be introduced and marketed without premarket Agency review or approval. However, in the case of new drugs, a New Drug Application (NDA) must be submitted to and approved by the FDA before the product may be legally marketed. The FDA, in determining the status of an NDA, must be satisfied that the new product is both safe and effective before it will approve the application. The Act defines a new drug as Any drug...the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed., in the labeling thereof.... Under

¹⁰ 51 Food & Drug L.J. 243, 255 (1996)

²¹ U.S.C. §321(p) (1938)

these guidelines, a toothpaste which merely uses the same ingredients in the same combination as another, previously approved toothpaste formula would not be classified as a new drug under the statute. Thus, manufacturers of such a product would avoid having to submit an NDA and could avoid FDA regulation as a new drug entirely. However, since toothpastes have become widely used, manufacturers have constantly sought new ingredients, and new combinations thereof, in an effort to further differentiate their product from the myriad others on the market and to attract the consumer to their brand because of its particular ingredients and abilities. This has caused some potential problems in the FDA conferring a much-unwanted new drug status upon certain toothpastes. In U.S. v. Articles of Drug... Promise Toothpaste¹², the court affirmed that certain toothpastes are indeed new drugs under the 1938 Act. The court explained that even if the component parts of a new drug are generally recognized as safe or effective, the combination of those parts may still be unsafe or ineffective.¹³ Thus, quantities of toothpaste containing this new combination of active ingredients and introduced into interstate commerce without an approved NDA were subject to forfeiture.¹⁴ An OTC drug be recognized as safe and effective after combining two or more safe and effective active ingredients only if the new drug meets the following three conditions: (1) each active ingredient makes a contribution to the claimed effect(s), (2) combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients, and (3) the combination, when used under adequate directions for use and

¹² 826 F.2d 564 (7th Cir. 1987)

¹³ .14~ at 3

¹⁴ j~ at 5

warning against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.¹⁵ In the Promise Toothpaste case, the court, using these criteria, ruled that Promise's combination of a single anticaries ingredient and another active ingredient is a new drug subject to the NDA requirements of the 1938 Act. According to the Promise Toothpaste case and the regulation, for combination toothpaste products, the manufacturer must likely get a new NDA approved for the product. Since this process is time-consuming and costly, and could potentially lead to denial of an NDA anyway, most manufacturers would like to avoid this step. In order to avoid this classification as a new drug under the statute, the manufacturer of a combination toothpaste must show that each ingredient contributes to the claimed effects, and that the combination does not make any of the individual components any less safe or effective.¹⁶

Safety Regulations for Toothpaste

In the Federal Register of October 6, 1995, the FDA established its final monograph for OTC anti-cavity drug products. This final monograph includes the conditions under which the products covered by the monograph will be considered safe and effective. In ensuring the safety of toothpaste, the FDA has established a number of regulations, relating to the required testing procedures before the product may be marketed, the size and type of packaging for the product, and the necessary ingredients and warnings on the

¹⁵ 21 C.F.R. §330.10(a) (4) (iv)

¹⁶ See U.S. v. Articles of Drug...Promise Toothpaste, 826 F.2d 564; ~ U.S. v. Seven Cardboard Cases...Capsules...With Codeine, 716 F.Supp. 1221, 1223

label.

The final monograph establishes two tests, one of which must be met by any toothpaste product before it is considered safe to be on the market for humans. Each product must satisfy either the enamel solubility reduction test or the fluoride enamel uptake test. Either of the two tests is sufficient to satisfy the safety requirement.¹⁷ The procedures for these tests are readily available at the FDA offices in Maryland. As part of these biological tests, the United States Pharmacopeia fluoride dentifrice reference standards and reference standard stability profiles (total fluoride, available fluoride ion, pH, and specific gravity) must be used, and these too are available at the FDA offices.¹⁸ Additionally, alternative tests may be used, provided that the manufacturer petitions the FDA with the vital data of these proposed tests and makes all required disclosures.¹⁹

In terms of toothpaste packaging, the FDA is concerned with the toxicity of fluoride, an active ingredient in almost all toothpastes due to its proven cavity-fighting power. Thus, the Agency has placed a package size limitation on all dentifrice (toothpaste and tooth powder) products. According to the final monograph, such products may not contain more than 276 milligrams of total fluoride per package.²⁰ This requirement is what keeps toothpaste tubes at their relatively small size. Additionally, the FDA also thought it important to avoid exposure of water and other moisture to certain toothpastes. Thus, all fluoride powdered toothpastes must be packaged in a tight container. This is defined in

¹⁷ 60 Fed. Reg. 52474(1995), as codified in 21 C.F.R. §355.70 (a) (1995)

¹⁸ §355.70(b)

¹⁹ §355.70(c)

²⁰ 60 Fed. Reg. 52474(1995), 21 C.F.R. §355.20(a) (1) (1995)

the section as a container that protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the article, and from efflorescence, deliquescence, or evaporation under ordinary conditions of handling, shipment, storage, and distribution. Such a container must also be capable of tight closure.²¹ The exception is that package size limitations do not apply to anticaries drug products marketed for professional office use only.²² §355.60(b) provides that the labeling of products marketed to health professionals in package sizes larger than those allowed in §355.20 must contain on the label For Professional Use Only and This product is not intended for home or unsupervised consumer use. Note also that dentifrices, along with dermatologics and insulin, are the only OTC drugs not subject to the FDA's tamper-resistant packaging requirement.²³

The final monograph for anticaries drug products also requires a number of disclosures to be prominently on the label of the product to ensure public safety. These requirements will be discussed in a later section, under Labeling.

Effectiveness Regulations for Toothpaste

The FDA also dealt with ensuring the effectiveness of toothpaste in its final monograph for anticaries drug products. Effectiveness is defined as a reasonable expectation that, when used under adequate directions and warnings, a significant proportion of the target

²¹ §355.20(b)

²² §355.20 (a) (3)

²³ 47 Fed. Reg. 50442(1982)

population will show significant relief of the type claimed.²⁴ Much as with the safety requirements, all toothpaste products must meet the animal caries reduction test before being marketed to humans.²⁵ In other words, the ingredients in every tube of toothpaste we see must first have been proven at least to reduce tooth decay in animals. This was a new requirement in the final monograph, and as a result, all products are expected to comply with this requirement by June 30, **1997.26** As with the required safety tests, §355.70(c) allows alternative effectiveness tests with the proper petition and approval. Additionally, the OTC Panel concluded in 1980 that if certain analytic and biologic tests are performed, and acceptable results are achieved, then clinical testing is not required because extensive clinical testing has previously been performed on the effectiveness of toothpaste products. The acceptable results are those obtained from other toothpastes that have already been proven to be clinically effective.²⁷ Note that if a toothpaste contains a combination of ingredients, as discussed above, then new clinical testing will be required to confirm the safety and effectiveness of this combination drug.

Labeling of Toothpaste

There are several regulations in the final monograph for anticaries drugs dealing with

²⁴ U.S. v. Articles of Drug...Promise Toothpaste, 826 F.2d 564 (7th Cir. 1987)

²⁵ 60 Fed. Reg. 52474 (1995), 21 C.F.R. §355.70(a) (1995)

²⁶ 61 Fed. Reg. 65944, 65945 (1996)

²⁷ 45 Fed. Reg. 20677 (1980)

the labeling of the products, some of which apply only to toothpastes, and others which apply more generally to all anticavity drug products (i.e. dentifrices, mouthwashes, oral rinses and gels, etc.). The first and perhaps most basic is the statement of identity, which must include the established name of the toothpaste, and must clearly identify the product as: anticavity fluoride (select one of the following as appropriate: dentifrice, toothpaste, tooth polish, or tooth powder; (optional: dental)).²⁸ The regulation provides the definition of dentifrice as An abrasive-containing dosage form (gel, paste, or powder) for delivering an anticaries drug to the teeth. As regards products which are arguably either cosmetics or drugs (such as some toothpastes discussed earlier), the FDA does not believe it necessary to include the phrase drug product on the label because the requirements for labeling only apply to drugs. If the product is indeed intended to be both a drug and a cosmetic, it must comply with the drug labeling requirements as well as those for cosmetics, found in 21 U.S.C. §362.

Next, all toothpaste labels must list Indication, followed by: Aids in the prevention of dental (select one of the following: cavities, decay, caries (decay), or caries (cavities)). **11131** Other non-misleading statements may be included under Indication provided that they describe this indication found in §355.50(b).

Toothpaste labels must also include warning statements. 21 C.F.R. §355.50(c)(1) (1995) provides that all fluoride dentifrices (toothpastes and tooth powders)

²⁸ 60 Fed. Reg. 52474, 52508(1995), as codified in 21 C.F.R. §355.50 (a) (1995)

²⁹ §355.30(e)

³⁰ 59 Fed. Reg. 5226, 5227(1994)

³¹ 21 C.F.R. §355.50(b) (1995)

must include the following statement: Keep out of the reach of children under 6 years of age. A recent addition to this warning is: If you accidentally swallow more than used for brushing, seek professional assistance or contact a Poison Control Center immediately.³² This is due to the constant controversy over the toxicity of fluoride in larger amounts than are normally ingested during brushing of the teeth.

21 C.F.R. §355.50(d) deals with directions on toothpaste labels. The heading must be marked Directions, and the required directions differ slightly depending on the total fluoride concentration of the active ingredients. See section labeled Ingredients for further discussion. According to the final monograph, the following statement must also be prominently placed on the principal display panel: IMPORTANT: Read directions for proper use.~

(1) For toothpastes with a theoretical total fluorine concentration of 850 to 1150 parts per million (ppm), the directions must read Adults and children 2 years of age and older:

Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor. Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.³ The word minimize is a recent change from the tentative final monograph, and was changed because, after performing studies on young children, the OTC panel concluded that children will often tend to swallow minute amounts of toothpaste during normal brushing.

³² 61 Fed. Reg. 52285, 52287 (1996)

~ §355.55

The previous version of the monograph spoke of prevention of swallowing instead of simply minimization, and the Panel concluded that there was no need to worry parents who observe their children swallowing small amounts of fluoride³

(2) For toothpastes with a theoretical total fluorine concentration of 1500 ppm, the directions include the same first sentence, but then also must include the following:

Instruct children under 12 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Do not use unless directed by a dentist or doctor.³⁶ These minor changes deal only with raising the recommended age for children to use products with such high concentrations of fluorine, because the toxicity and danger of fluorosis is increased in younger children. An optional direction statement for such high-concentration fluoride toothpaste products is: Adults and children over 6 years of age may wish to use this extra-strength fluoride dentifrice if they reside in a nonfluoridated area or if they have a greater tendency to develop cavities.³⁷

(3) For powdered toothpastes with a theoretical total fluorine concentration of 850 to 1150 ppm, the required directions contain much the same age restrictions as the higher-concentration toothpastes in part (2) above, along with specific directions on how to use the powdered pastes themselves.~

In the early to mid 1980's, Crest and Colgate were the first to introduce 'Tartar Control

- ~ 60 Fed. Reg. 52474, 52488(1995) 36 355.50(d) (ii)
- ~ §355.50(f) (2)
- ~ §355.50(d) (iii)

toothpaste, making anti-tartar and anti-plaque claims about their products. The FDA says that it has not objected to plaque reduction claims when the reduction of plaque is based on the abrasive action of the dentifrice during brushing but has objected recently where such claims are attributed to one or more of the toothpaste's active ingredients. ~ The Agency did not take action against anti-tartar toothpastes when they first were marketed in 1983, viewing such claims as purely cosmetic, rather than drug claims subject to strict regulation. ~ This lack of action was based on the fact that supragingival (above the gumline) tartar does not lead to disease, while subgingival tartar does. Thus, reasoned the FDA, a toothpaste that claims to reduce supragingival tartar is not making a disease-prevention claim, but rather merely a cosmetic one. Therefore, the FDA OTC Committee has ruled that anti-tartar products should say on the label that the substances only affect supragingival tartar and have no therapeutic effect on gingivitis (gum disease) if the manufacturer wants these claims to have purely cosmetic status. Further, the Agency will consider all unqualified tartar claims to be drug claims.⁴¹

All toothpastes, like other OTC drugs, are subject to the other labelling requirements of 21 U.S.C. §352(1938) as well. §352(a) explains that a drug is deemed misbranded, and thus may not be entered into interstate commerce, if its labeling is false or misleading in any particular. This is why we do not see toothpastes on the market which claim on the label to guarantee no cavities during the user's lifetime, or other similarly ridiculous claims. §352(b) indicates that the package containing the drug (in this case, the pump or tube

~ The Rose Sheet, Mar. 18, 1996

40 The Pink Sheet, November 13, 1989

41 The Rose Sheet, April 17, 1995

of toothpaste) must include the name and address of the manufacturer, packer, or distributor⁴² and an accurate statement of the weight, measure, or numerical count of the contents of the package⁴. Thus, toothpastes usually contain on the label the net weight of the tube or pump.

Ingredients of Toothpaste

21 U.S.C. §352 (1938), dealing with misbranded drugs or devices, also contains a final requirement that a drug is deemed misbranded unless it contains the established name of the drug (i.e. the active ingredient), or, in the case of combination drugs discussed earlier, the established name and quantity of each active ingredient. The final monograph for anticaries drug products provides guidance as to what drugs and dosages of each will be accepted by the FDA as the active ingredient for toothpastes. 21 C. F. R. §355.10(1995) provides for three different acceptable active ingredients. First, sodium fluoride may be used, with .188 to .254 percent sodium fluoride (in paste or powdered form), with slightly higher requirements of available fluorine ion in the powder than in the paste. Secondly, sodium monofluorophosphate has also been approved by the Panel, in .654 to .884 percent concentration for dentifrices containing average amounts of fluorine, or in a 1.153 percent concentration for high-fluorine formulas. Lastly, the OTC Panel has also approved toothpastes with stannous fluoride as the active ingredient, in .351 to .474 percent concentration, and with lower available fluorine ion requirements in formulas containing

⁴² §352(b) (1) (1938)

~ §352(b) (2)

calcium pyrophosphate than in those using a different element as an abrasive.

There has also been much regulation regarding the use of colored dyes in toothpastes. D&C Red No. 8 and No. 9, which were approved for use in dentifrices in 1983⁴⁶, were then prohibited from being added to dentifrices and mouthwashes after January 5, 1987⁴⁷. D&C Red No. 33 and No. 36 are similarly prohibited from use in mouthwashes and toothpastes, though they have been approved for other ingested drugs.⁴⁷ FD&C Red No. 40, however, has been approved for use in dentifrices that are cosmetics⁴⁸ and eventually for cosmetics generally⁴⁹. Similarly, D&C Orange No. 5 has been approved for drug and cosmetic dentifrices.⁵⁰ D&C Orange No. 17 has been approved for use in dentifrices, but only at not more than .002 percent of the pure dye by weight of the dentifrice.⁵¹ FD&C Yellow No. 5 may also be used in dentifrices that are drugs and cosmetics, and the labels of these dentifrices need not necessarily declare the presence of this dye, as must other products.⁵²

Another ingredient permitted to be used in the manufacture of toothpastes is mica. The FDA ruled in 52 Fed. Reg. 29664(1987) that it is safe to use mica in toothpastes that are

~ §355.10 (a) (1)—(2) (1995)

~ 48 Fed. Reg. 13976, 13978(1982)

⁴⁶ 51 Fed. Reg. 43877(1986)

~ 53 Fed. Reg. 33110, 33120(1988) and 53 Fed. Reg. 29024, 29031 (1988)

⁴⁸ 39 Fed. Reg. 28278(1974)

~ 39 Fed. Reg. 44198(1974)

~ 49 Fed. Reg. 31852(1984)

~ 48 Fed. Reg. 5262, 5264(1983)

⁵² 50 Fed. Reg. 23815, 23817(1985)

cosmetics as well as drugs, in response to a petition from the Procter and Gamble company. Sodium is also permitted (see Ingredients), and toothpastes and mouthwashes are exempt from the labeling requirement (listing the amount of sodium in the product) since these products are not intended for oral ingestion. At this time, insufficient data has been brought to the attention of the FDA as to the absorption of sodium when these products are used to warrant a sodium labeling requirement.~

The Fluoride Issue

A specific ingredient found in toothpastes that has come under much debate due to its toxicity is fluoride. Humans, mostly children, are at risk of developing fluorosis of the teeth if exposure to fluoride is not curbed at some point, which can leave teeth greatly discolored and stained. The FDA, using a cost-benefit analysis, thus feels that children under 6 should not use toothpastes exceeding 1150 ppm of total fluoride.^{5'} The Agency, however, has determined that a 1500-ppm theoretical total fluoride level is safe for children over 6 and for adults (based on two clinical studies), approving an NDA for such an extra-strength fluoride dentifrice in 1986. However, since fluorosis is increasing among children in this country, the FDA cautions against those below the age of 6 from using such products. The Agency has also ruled that fluoride levels above 1 500 ppm have not been proven safe and effective, and thus they were excluded from the final monograph for anticaries drug

~ 61 Fed. Reg. 17798, 17800(1996)

~ 60 Fed. Reg. 52474, 52479(1995)

Id.

⁵⁶ Id. at 52483

products⁵⁵ The FDA, after extensive testing, has also stated that presently there is not enough evidence to show that a low-fluoride dentifrice is safe and effective for children 2 to 6 years old, or to determine the proper fluoride concentration for such a low-level dentifrice, and thus these too have been left out of the final monograph. Note as well that, despite this ongoing debate, the final monograph for anticaries drug products still contains no requirement that toothpastes containing fluoride label the quantity of fluoride within the product. ~

International Regulation of Toothpaste

Many of the same issues facing the FDA in America are also being faced currently by other advanced countries as they attempt to protect their citizens from the possible evils of misbranded or poorly formulated drugs. This issue is especially important with a product such as toothpaste, which is placed in the mouth and has the potential to be ingested. England, for instance, recently went through an incident which may lead to increased labeling regulation of fluoride-containing toothpastes. Colgate-Palmolive agreed to make a settlement payment to a family whose child had his teeth permanently discolored as a result of the same fluorosis problem that has concerned the FDA in this country. In fact, now more than 300 British families are making similar claims against

toothpaste manufacturers.⁵⁷ As a result of these claims, leading supermarket chains in England are considering introducing new fluoride-free toothpastes themselves and adding warnings against swallowing the product on toothpaste labels, which do not currently exist. Current labeling requirements in England require instructions that only a pea-sized amount should be used, and that children under 7 years of age should be supervised when brushing their teeth.⁵⁵ Additional regulations require that manufacturer's claims merely be not misleading, since toothpastes fall under cosmetic and not medical regulations.⁵⁵ A spokesman for the Department of Health, however, says there are no plans to change the current level of governmental regulation.

The European Union, facing similar problems, strictly regulates cosmetic products, which include toothpastes. These regulations, much like in America, focus largely on the composition and labeling of such products. The EU has also established a post with the power to receive complaints from any citizen of the EU with a consumer issue.~ Canada has similar standards for which claims may be made on labels, and for strengths of sodium fluoride, acidulated phosphate fluoride, and stannous fluoride. In Canada, manufacturers may make various cavity-prevention claims, but several warnings are required on oral care products. These include warnings against swallowing the product, and that children

~ Jackson, Linda, Toothpaste to carry chemical warning, The Sunday Telegraph, London, Sunday Dec. 1, 1996

~ Bloor, Caroline, Consumer News: Brushing Up on a Whiter Smile, The Daily Telegraph, London, Monday, Feb. 26, 1996

60 Lansman, Nicholas, Consumer Protection in the EU, ~ap Perfumery & Cosmetics, Monday, July 1, 1996

should be supervised when using toothpaste.⁶¹

In Singapore, June 1997 marks the deadline after which all cosmetic products, including toothpastes, will have to bear content labels for the first time. These measures are designed to protect members of the public from using products containing ingredients to which they are allergic, as well as to help doctors determine which substances cause allergic reactions in their patients. All cosmetic products in Singapore will also have to contain batch numbers for the first time.⁶² The country's Health Ministry says it will be illegal to manufacture, import, sell, or supply any cosmetic product that does not meet these new specifications.

Conclusion

It can be seen that the FDA indeed imposes rather strict regulations on toothpaste products in this country. For the purpose of fulfilling its mission to protect the public from unsafe and ineffective products, fluoride toothpaste is regulated as a drug under the 1938 Food Drug and Cosmetic Act. The FDA attempts to ensure the safety of toothpastes by requiring certain testing, and by regulating the ingredients used in the product, as well as the packaging and the warnings thereon. The Agency also uses testing procedures and various standards to be sure the toothpastes on the market are effective. The OTO drug review resulted in a final monograph for anticaries drug products in late I 995, and this

⁶¹ ~ Oral Care Products: Canada-New Labeling Regulations, Sunday, Sep. 1, 1996

⁶² All cosmetic products to show contents, some to be licensed, Singapore Straits Times, Saturday, June 15, 1996

monograph provides the three acceptable active drugs for use in toothpaste products, as well as other allowable ingredients. Strict labeling requirements are also promulgated in the C.F.R. for toothpastes, to ensure that the public is given all the information deemed necessary by the OTC Panel. Finally, it is apparent that the FDA imposes similar, if not more stringent, requirements on its toothpaste manufacturers than other countries impose on theirs, mostly dealing with the labeling and composition of toothpaste products. One can only hope that the stringency of these requirements will continue to protect the American people from a major toothpaste scare, as have occurred with various other consumer products over the last few decades.